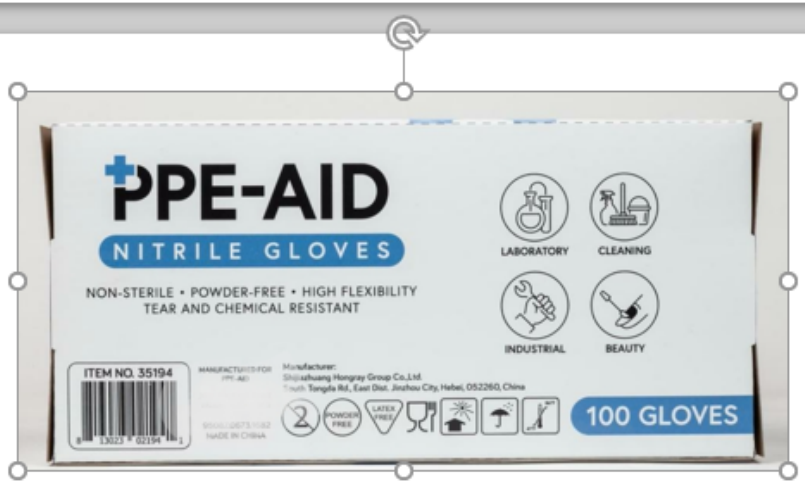
PPE AID NITRILE GLOVES

- 510K CERTIFIED
- FDA APPROVED
- EXAM GRADE
- POWDER FREE


PPE-AID
NITRILE GLOVES
MEDIUM
NON-STERILE • POWDER-FREE • HIGH FLEXIBILITY
TEAR AND CHEMICAL RESISTANT
100 GLOVES


PPE-AID
NITRILE GLOVES
NON-STERILE • POWDER-FREE • HIGH FLEXIBILITY
TEAR AND CHEMICAL RESISTANT
LABORATORY
CLEANING
INDUSTRIAL
BEAUTY
ITEM NO. 35194
100 GLOVES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PPE-AID
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SGS

Test Report No.: SHHL1602075366MD-01 Date: OCT. 06, 2020 Page: 1 of 8

SHIJIAZHUANG HONGRAY GROUP CO., LTD
SOUTH TONGDA RD., EAST DIST. JINZHOU CITY, HEBEI, 052260, CHINA

THE TEST REPORT IS TO SUPERSEDE THE TEST REPORT No.: SHHL1602075366MD DATE: SEP. 28, 2020
The following sample(s) was/were submitted and identified by the client as:

Sample Description	: DISPOSABLE NITRILE GLOVE
Style/ Item No.	: XS,S,M,L,XL,XXL
Country of Origin	: CHINA
Sample Receiving Date	: AUG. 29, 2020
Testing Period	: AUG. 29, 2020 TO SEP. 28, 2020
Test Performed	: SELECTED TEST(S) AS REQUESTED BY APPLICANT
Test Requested	: 1. EN 455-1:2000 MEDICAL GLOVES FOR SINGLE USE – PART 1: REQUIREMENTS AND TESTING FOR FREEDOM FROM HOLES 2. EN 455-2: 2000 MEDICAL GLOVES FOR SINGLE USE – PART 2: REQUIREMENTS AND TESTING FOR PHYSICAL PROPERTIE 3. EN 455-3: 2000 MEDICAL GLOVES FOR SINGLE USE— PART 3: REQUIREMENTS AND TESTING FOR BIOLOGICAL EVALUATION CLAUSE 4.4 & 4.6
Test Result(s)	: FOR FURTHER DETAILS, PLEASE REFER TO THE FOLLOWING PAGE(S)
Conclusion	: THE SUBMITTED SAMPLE MET THE TEST REQUIREMENT.

****

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.

Vincent Feng
Technical Manager

Test Conducted:

1. EN 455-1:2000 Medical gloves for single use – part 1: Requirements and testing for freedom from holes

Number of test sample	:	200 Pieces
The type of gloves	:	examination/procedure gloves
Manufacturing batch code	:	/
Batch size	:	/
Sample size	:	XS, S, M, L, XL, XXL
Number of non-conforming gloves	:	None
Defects observed before testing	:	No defects
Test Result	:	Pass

Clause	Test Items	Result	Note
5	Watertightness test for detection of holes	---	---
5.1	Referee testing		# 1&2

2. EN 455-2:2000 Medical gloves for single use – part 2: Requirements and testing for physical propertie

Number of test sample	:	104 Pieces
Type	:	examination/procedure gloves
The manufacturing batch code	:	/
Size	:	XS, S, M, L, XL, XXL
Defects observed before testing	:	No defects
Test Result	:	Pass

Clause	Test Items	Result	Note
4	Dimensions	Pass	#3
5	Strength	Pass	#1&4
7	Labeling	Pass	/

3. EN 455-3: 2000 Medical gloves for single use—Part 3: Requirements and testing for biological evaluation

Number of test sample	:	5 Pieces
Finishes of gloves	:	Powdered-free gloves other than surgeon's gloves
Defects observed before testing	:	No defects
Test Result	:	Pass

Clause	Test Items	Result	Note
4.4	Powder	Pass	#1, 5&6
4.6	Labeling	Pass	/

Note:
1. As per client's declare, these gloves (four size: XS, S, M, L, XL, XXL) only size different, the material is the same, and only the glove of size M was tested.
2. See result 1.
3. See result 2.
4. See result 3.
5. Test according to EN ISO 21171-2006.
6. The powder of sample was 0.3mg<2mg.

Test Results:

1. Watertightness test for detection of holes

Sample Quantity: 200pcs

AQL: 1.5 Accept: 7 Reject: 8 Found: 0

2. Dimensions

Sample Quantity: 78pcs

Size	XS												
Length(mm)	253	253	253	254	252	255	256	254	253	254	252	253	253
Width(mm)	79	78	79	77	78	77	78	77	78	79	78	79	78

Median value:

Length (mm): 253
Width (mm): 78

Size	S												
Length(mm)	245	244	242	243	244	246	245	244	245	246	244	243	243
Width(mm)	88	85	87	86	88	87	86	88	87	88	87	86	85

Median value:

Length (mm): 244
Width (mm): 87

Size	M												
Length(mm)	244	245	245	246	245	247	246	245	244	245	246	247	246
Width(mm)	96	95	97	96	95	97	96	96	95	96	97	96	97

Median value:

Length (mm): 245
Width (mm): 96

Size	L												
Length(mm)	243	242	241	242	243	242	242	242	242	243	241	242	243
Width(mm)	109	108	107	109	108	107	108	107	108	109	108	107	107

Median value:

Length (mm): 242
Width (mm): 108

Size	XL												
Length(mm)	249	248	250	249	247	248	249	248	248	249	248	249	248
Width(mm)	114	113	114	115	113	114	115	115	114	115	116	114	115

Median value:
Length (mm): 248
Width (mm): 114

Size	XXL												
Length(mm)	245	246	244	244	245	246	245	246	246	245	245	244	243
Width(mm)	119	118	120	119	118	119	118	120	119	118	119	120	119

Median value:
Length (mm): 245
Width (mm): 119

Requirements: see table 1&2

Table 1 Dimensions for surgical gloves

Size	Median length in mm	Median width in mm
5	≥250	67±4
5.5	≥250	72±4
6	≥260	77±5
6.5	≥260	83±5
7	≥270	89±5
7.5	≥270	95±5
8	≥270	102±6
8.5	≥280	108±6
9	≥280	114±6
9.5	≥280	121±6

Table 2 Dimensions for examination/procedure gloves

Size	Median length in mm	Median width in mm
Extra small	≥240	≤80
Small		80±10
Medium		95±10
Large		110±10
Extra Large		≥110

3. Strength

Sample Quantity: 26pcs

Size	M												
Force at break(N)	9.19	8.79	9.27	9.02	8.25	9.35	9.27	9.36	8.98	8.38	9.02	8.90	9.58
Force at break after challenge testing(N)	9.41	9.50	9.50	9.38	9.58	9.46	9.23	9.38	9.77	9.50	9.58	9.18	9.65

Median value:

Force at break during shelf life (N): 9.02
Force at break after challenge testing (N): 9.50

Table 3 — Median values of force at break

	Force at break in Newton		
	Surgical gloves a)	Examination/procedure gloves b)	c)
Throughout shelf life tested according to 5.2 and within 12 months of manufacture tested according to 5.3	≥ 9,0	≥ 6,0	≥ 3,6

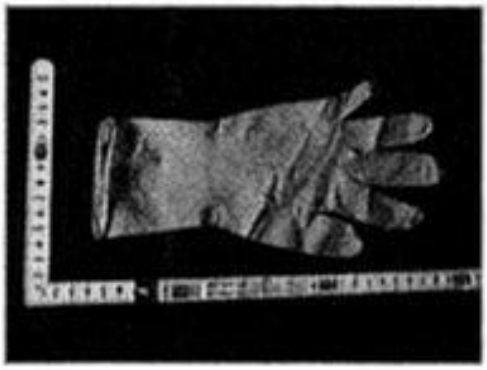
a) Requirements for all surgical gloves.
b) Requirements for all examination gloves, except gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).
c) Requirements for gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).

Remark:

1. The sample selecting amount for Watertightness test for detection of holes is deviated to 200 pcs as accessed by SGS.

Sample Photo:

Received sample (size XS)

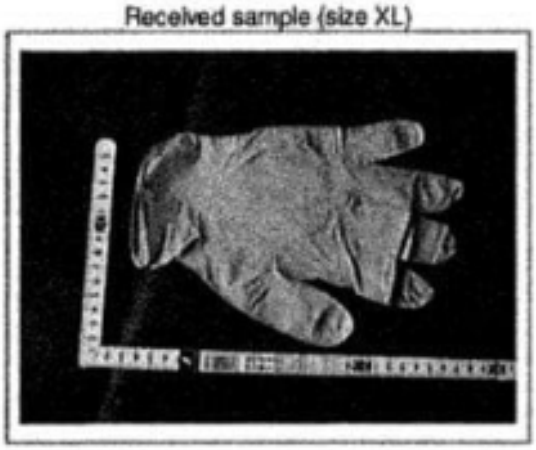


Received sample (size S)

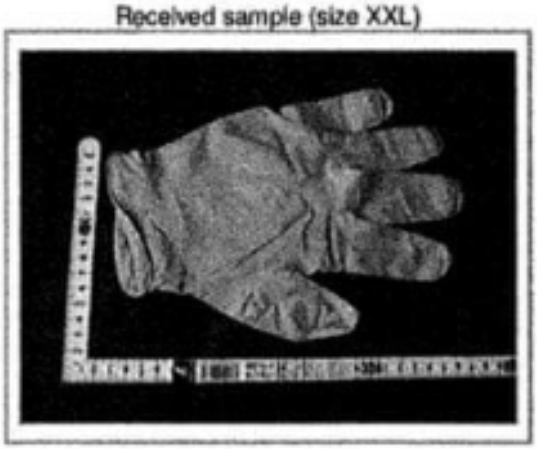
Received sample (size M)

Received sample (size L)

Received sample (size XL)



Received sample (size XXL)



SGS authenticate the photo on original report only

End of Report

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中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-400 820 9661 f (86-21) 6115 5899 e sgs.china@sgs.com

U.S. FOOD & DRUG ADMINISTRATION

November 30, 2018

[redacted] Plastic Technology Co., Ltd
[redacted] Liu
[redacted]
[redacted]
3973 Schaefer Avenue, Chino, CA 91810, USA

Re: K182600
Trade/Device Name: Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class 1
Product Code: LZA, LZC
Dated: September 16, 2018
Received: September 21, 2018

[redacted] Liu:

We have revi[redacted]premarket notification of intent to market the device referenced above and have determi[redacted]nt (for the indications for use stated in the enclosure) to legally marketed predicate devices [redacted] the enactment date of the Medical Device Amendments, or to devices that [redacted] in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

[redacted]